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Award Number: W81XWH-07-1-0001

TITLE: Alaska Native Parkinson's Disease Registry

PRINCIPAL INVESTIGATOR: Brian A. Trimble, M.D.

CONTRACTING ORGANIZATION:
Alaska Native Tribal Health Consortium
4000 Ambassador Dr.
Anchorage, AK 99508-5909

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13. SUPPLEMENTARY NOTES

14. ABSTRACT: This registry initiates a program of epidemiological assessments of PS among Alaska Natives to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Natives may be estimated as well. This registry not only would facilitate future research into PS etiology, but also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period and is well underway at this time. During this phase, we are established the data collection and dissemination protocols, regulatory submissions are under review for the registry to obtained necessary approvals, the registry database is under development and a pilot project in Anchorage will be initiated pending approvals. Phase 2 has not yet begun. It is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

15. SUBJECT TERMS
Alaska Native; Parkinson's disease; Registry; Etiology; Epidemiology; Ascertainment

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A. Introduction

Parkinsonism (PS) is a syndrome characterized by tremor, rigidity, slowness of movement, and problems with walking and balance. Parkinson's disease is the most common form of PS, accounting for about 1% of the U.S. population over age 50 years. Little information is available about trends in PS, particularly in Alaska Natives.

This registry initiates a program of epidemiological assessments of PS among Alaska native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols are being established, necessary approvals for the registry are being obtained, and a pilot project in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

B. Body

The intent of this proposal is to establish a registry of Parkinsonism cases among Alaska native people living in Alaska, documenting cases' clinical features and management. Our goal is to use this registry to shed light on the frequency and natural history of PS in this population, as well as to reduce the burden of disease for patients and caregivers by minimizing side effects of therapy, identifying and treating co morbid conditions, identifying currently undiagnosed cases of PS, and educating patients and care providers about optimal management of PS. To do this, the following milestones are being accomplished:

SCOPE OF WORK

Phase 1, Development and Pilot Study:

Task 1: Establishing the scientific steering committee.
Accomplishments:
The scientific steering committee was established. The members include Drs. Trimble, Tanner, Ferucci, and Ross. Dr. Gordon, originally on the scientific steering committee has since passed away.

Task 2: Developing an identification protocol. The primary source of PS cases will be the Indian Health Service (IHS) provider database, called the Resource and Patient Management System (RPMS), but the protocol will include identifying other possible sources that would identify other cases of Parkinsonism among Alaska Natives.

Accomplishments:
We developed a protocol to search for approximately 30 ICD-9 codes within RPMS to identify any potential cases of PS. The protocol includes a method for electronically extracting the potential cases from RPMS to enable researchers to abstract available information from the RPMS database or paper charts for potential cases.

In addition to the RPMS searches, an additional ascertainment method has been developed. Cases will also be identified through searches of the AK Tribal Health System pharmacy database. Registry staff will search the pharmacy database for commonly prescribed PS medications. The search will be limited to medications filled within the previous 6 months. Since each medication is linked to a diagnostic code, these codes will be cross referenced with the ICD-9 diagnostic codes of interest

Task 3: Developing a secure Alaska Native PS registry database.
Accomplishments:
A contract was established with Peter Torkelson, owner of Advanced Design, to design the web-based database. Mr. Torkelson designed the Alaska Native Stroke Registry database which is serving as a template for the Alaska Native Parkinsonism Registry (ANPR) database. Meetings were held with Mr. Torkelson to discuss issues unique to the ANPR and review the necessary data elements. We refined the data elements and flow on paper. Given subsequent delays in obtaining regulatory approval, further implementation of the web-based ANPR database is pending regulatory approval to begin registry activities in Anchorage. Once regulatory approval is achieved, Mr. Torkelson will finalize the web-based database.

Task 4: Ascertaining needs and interests of the Alaska Native community with regard to PS registry project.
Accomplishments:
This activity is ongoing in the Anchorage service area as we refine our pilot protocols and have face-to-face meetings in Anchorage. A total of 4 face-to-face meetings have occurred in Anchorage. Pending IRB and Tribal approvals, we will expand the ascertainment of needs and interests outside of the Anchorage area.

Task 5: Developing a preliminary proposal for review by Alaska Native tribal organizations. Subsequent more detailed versions of the protocol will be submitted for review as they are developed as well.
Accomplishments:
A detailed surveillance protocol was developed and reviewed by the AK Area IRB and the privacy officer at the Alaska Native Tribal Health Consortium. Following this review, it was determined that to proceed efficiently given the number of boards required to give approval, the protocol should include research as well as surveillance aims.

The ANPR protocol has been revised to reincorporate the surveillance and research aims of the project.

Task 6: Establishing appropriate infrastructure and personnel in Alaska.
Accomplishments:
Contracts were established with 2 institutions, the Parkinson's Institute and the Pacific Health Research Institute, which are providing guidance on protocol development as needed to obtain regulatory approvals and development of detailed medical records abstraction procedures and diagnostic expertise. The Parkinson's Institute is also project management services. Ms. Stephens was brought on as a coordinator for this registry. She works at the AK Native Medical Center as a coordinator for the Alaska Native Stroke registry. Her extensive knowledge of the stroke registry protocols and daily activities are invaluable as the Parkinsonism registry is being modeled after the stroke registry. In an effort to conserve funds, we opted not to hire additional personnel while we are waiting for regulatory approvals as this process can take extended periods of time.

Task 7: Developing detailed data collection and management procedures.
Accomplishments:
A method was developed for electronically extracting potential case data from RPMS to enable researchers to abstract necessary information from the RPMS database or paper charts for potential cases. A steering committee meeting was held on December 13, 2007. Registry personnel worked with Peter Torkelson to identify data management and reporting needs. Ms. Stephens was hired to help modify data collection and management procedures used in the ongoing stroke registry as appropriate for the Parkinsonism registry.

Task 8: Developing detailed medical records abstraction protocols for data on clinical features, co morbid conditions, clinical management, and factors possibly affecting clinical management (e.g., home environment).
Accomplishments:
Several fields have been added to the abstraction tool including incorporating the collection of selected fields from the newly reformatted Unified Parkinson's Disease Rating Scale (UPDRS). The hiring of Ms. Stephens will also facilitate the modification of stroke registry protocols for use with the Parkinsonism registry.

Task 9: Working with communities to develop a multilevel educational program for health care providers, patients, and caregivers, addressing PS identification and management.
Accomplishments:
Following the pilot phase, we will begin focusing on Task 9.

Task 10: Refining the study protocol and preparing the operations manual.
Accomplishments:
This work is ongoing as we incorporate feedback from regulatory entities and local experts. Ms. Stephens was hired to assist in the preparation of the operations manual. Many modifications have been made to the study protocol as we continue to work with

involved regulatory entities. Additional refinements will occur following the conduct of the pilot in Anchorage.

Task 11: IRB approval and Alaska Native tribal organization feedback on and approvals of final protocols.
Accomplishments:
A detailed surveillance protocol was developed and reviewed by the AK Area IRB and the privacy officer at the Alaska Native Tribal Health Consortium. Following this review, it was determined that to proceed efficiently given the number of boards required to give approval, the entire protocol should be reviewed as one submission and should therefore include both research and surveillance aims.

The ANPR protocol has been revised to reincorporate the surveillance and research aims of the project.

Task 12: Pilot registry project among Alaska Natives residing in Anchorage Service Unit.
Accomplishments:
Task 12 activities are pending approval of the revised registry protocol.

Task 13: Initial implementation of educational program.
Accomplishments:
Task 13 activities are pending approval of the revised protocol.

Task 14: Monitor quality and completeness of registered data, and define data collection challenges.
Accomplishments:
This work has not been initiated. It will follow regulatory approval and data collection.

Phase 2, Registry Implementation:
When the tasks of the development phase have been completed, we will expand the collection of PS registry data to Alaska Natives statewide. The specific tasks for this phase will include:
   1. Abstracting information from medical records of prevalent and incident PS cases into the PS registry.
   2. Continuing implementation of educational program for health care providers, patients, and caregivers.
   3. Reporting, analysis and publication.

C. Key Research Accomplishments

- Met with collaborating neurologists in AK, other local investigators, and Parkinson's Institute staff to refine methods of case ascertainment.
- Interactions with the Alaska Area IRB representatives and a compliance reviewer at the DOD to revise the protocol.
- Second submission of the registry protocol to the AK Area IRB.
- Continued revisions to registry abstraction tool and protocols to satisfy the requests of the reviewers and the needs of the web-based database.

D. Reportable Outcomes

While many milestones of phase 1 of this project were met, we are still in the process of obtaining approvals necessary to begin data collection. Until this has been accomplished and state wide data has been collected, we will not have reportable outcomes.

E. Conclusions

Phase 1 of this project is well underway. We have encountered challenges in determining an appropriate and efficient course for satisfying the regulatory needs for this project although we anticipate overcoming this in the coming months.   Following the completion of state wide data collection (Phase 1 and 2) and analysis, it will be possible to draw relevant scientific conclusions.

F. References
None

G. Appendices
A copy of the current abstraction tool is enclosed.

APPENDICES

ANPR ABSTRACTION FORM

PATIENT INFO (add 'not available choice for each of the patient info fields)
MEDICAL RECORD NUMBER:
PS Registry ID:
FNAME:
LNAME:
DOB:
Address:
Phone1:_____ Type: O Home O Cell O Other
Phone2:_____ Type: O Home O Cell O Other
Ethnicity: O Aleut O Yupik O Inupiat O Tlinket O Haida O Tsimshian O Athabascan
Education: O < High school O High school grad (or GED) O Trade school O Some college O College grad O Graduate/Professional degree

PRIMARY HEALTH SERVICE CLINIC:_____

CURRENT VITAL STATUS: O Alive O Deceased O DK
If deceased:
Death Date:
Death Source:
Death location:

ABSTRACTOR INFO
ABSTRACTED BY: O TRIMBLE O OTHER, specify _____
ABSTRACTION DATE:

INFORMATION SOURCE(S) Select all that apply:
      0 Medical records: 0 Neurologist   0 Non-Neurologist
      0 Death certificate: _____(ICD code)

CLINICAL SIGNS OR SYMPTOMS:

A. Parkinsonism

Resting tremor	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
Rigidity	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
cogwheeling?	O Yes O No O Questionable O DK
Bradykinesia	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
Postural reflex impairment	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK

Asymmetric onset of Parkinsonian signs   O Yes O No O Questionable O DK O N/A
Asymmetry, ever of Parkinsonian signs   O Yes O No O Questionable O DK O N/A

Was there a substantial and sustained
response to levodopa or a dopamine agonist?   O Yes O No O Questionable O Did not take O Inadequate trial O Unknown

Progressive Disorder?   O Yes O No O Questionable O DK
    If Yes: O Yes O No O Questionable O DK

Other supportive features for Parkinson's disease: O Yes O No O Questionable O DK

a. stooped posture	0 Yes	0 No	0 Questionable	0 DK
b. decreased arm swing	0 Yes	0 No	0 Questionable	0 DK
c. shuffling gait	0 Yes	0 No	0 Questionable	0 DK
d. micrographia	0 Yes	0 No	0 Questionable	0 DK
e. diminished olfaction	0 Yes	0 No	0 Questionable	0 DK

f. seborrheic dermatitis	0 Yes	0 No	0 Questionable	0 DK

Hallucinations and Psychosis
0: Normal: No hallucinations or psychotic behavior.
1: Slight: Illusions or non-formed hallucinations, but patient recognizes them without loss of insight.
2: Mild: Formed hallucinations independent of environmental stimuli. No loss of insight.
3: Moderate: Formed hallucinations with loss of insight.
4: Severe: Patient has delusions or paranoia.

Light headedness on standing
0: Normal: No dizzy or foggy feelings.
1: Slight: Dizzy or foggy feelings occur. However, they do not cause me troubles doing things.
2: Mild: Dizzy or foggy feelings cause me to hold on to something, but I do not need to sit or lie back down.
3: Moderate: Dizzy or foggy feelings cause me to sit or lie down to avoid fainting or falling.
4: Severe: Dizzy or foggy feelings cause me to fall or faint.

Eating tasks
0: Normal: Not at all (No problems).
1: Slight: I am slow, but I do not need any help handling my food and have not had food spills while eating.
2: Mild: I am slow with my eating and have occasional food spills. I may need help with a few tasks such as cutting meat.
3: Moderate: I need help with many eating tasks but can manage some alone.
4: Severe: I need help for most or all eating tasks.

Dressing
0: Normal: Not at all (no problems).
1: Slight: I am slow but I do not need help.
2: Mild: I am slow and need help for a few dressing tasks (buttons, bracelets).
3: Moderate: I need help for many dressing tasks.
4: Severe: I need help for most or all dressing tasks.

Hygiene
0: Normal: Not at all (no problems).
1: Slight: I am slow but I do not need any help.
2: Mild: I need someone else to help me with some hygiene tasks.
3: Moderate: I need help for many hygiene tasks.
4: Severe: I need help for most or all of my hygiene tasks.

Tremor
0: Normal: Not at all. I have no shaking or tremor.
1: Slight: Shaking or tremor occurs but does not cause problems with any activities.
2: Mild: Shaking or tremor causes problems with only a few activities.
3: Moderate: Shaking or tremor causes problems with many of my daily activities.
4: Severe: Shaking or tremor causes problems with most or all activities.

Getting out of bed, car, or deep chair
0: Normal: Not at all (no problems).
1: Slight: I am slow or awkward, but I usually can do it on my first try.
2: Mild: I need more than one try to get up or need occasional help.
3: Moderate: I sometimes need help to get up, but most times I can still do it on my own.
4: Severe: I need help most or all of the time.

Walking balance
0: Normal: Not at all (no problems).
1: Slight: I am slightly slow or may drag a leg. I never use a walking aid.
2: Mild: I occasionally use a walking aid, but I do not need any help from another person.
3: Moderate: I usually use a walking aid (cane, walker) to walk safely without falling. However, I do not usually need the support of another person.
4: Severe: I usually use the support of another person to walk safely without falling.

Freezing
0: Normal: Not at all (no problems).
1: Slight: I briefly freeze but I can easily start walking again. I do not need help from someone else or a walking aid (cane or walker) because of freezing.
2: Mild: I freeze and have trouble starting to walk again, but I do not need someone's help or a walking aid (cane or walker) because of freezing.
3: Moderate: When I freeze I have a lot of trouble starting to walk again and, because of freezing, I sometimes need to use a walking aid or need someone else's help.

4: Severe: Because of freezing, most or all of the time, I need to use a walking aid or someone's help.

Peter: automated N/A for fields that are not applicable based on skip pattern

Exclusion criteria O Prominent postural instability in the first 3 years
For PD: O Freezing in the first 3 years
                                      O Hallucinations unrelated to medications in the first 3 years
                                      O Dementia Preceding motor symptoms or in the first year
                                      O Supranuclear gaze palsy other than restricted upward gaze or slowed vertical saccades
                                      O Severe, symptomatic dysautonomia unrelated to medications.
                                      O secondary cause of parkinsonism identified. If yes, specify

Signs or symptoms suggestive of movement disorders additional or *alternative to* **PD:**
     O Yes   *Complete any appropriate sections that apply*
     O No   *SKIP to FINAL DISPOSITION*
     O Questionable   *Complete any appropriate sections that apply*
     O DK   *SKIP to FINAL DISPOSITION*

B. Features related to a diagnosis of DEMENTIA, esp. dementia with Lewy bodies

Cognitive impairment sufficient to interfere with normal social or occupational function:	O Yes	O No	O Questionable	O DK
Prominent memory type disturbance (for Alzheimer type dementia):	O Yes	O No	O Questionable	O DK
Fluctuating cognition with variation in attention and alertness:	O Yes	O No	O Questionable	O DK
Visual hallucinations	O Yes	O No	O Questionable	O DK

Other supportive features for DLB: O Yes O No O Questionable O DK (If yes or questionable indicate all that apply)
- O Repeated falls
- O Transient loss of consciousness
- O Neuroleptic sensitivity
- O Systematized delusions
- O Hallucinations in other modalities

C. Features related to a diagnosis of PROGRESSIVE SUPRANUCLEAR PALSY

Gradually progressive disorder	O Yes	O No	O Questionable	O DK
Vertical supranuclear gaze palsy	O Yes	O No	O Questionable	O DK
Fails within first year of onset	O Yes	O No	O Questionable	O DK
Onset age 40 or later	O Yes	O No	O DK	

Other supportive features for PSP O Yes O No O Questionable O DK   (*IF Yes or **Questionable indicate** all that apply)*
- O Symmetric akinesia or rigidity, proximal more than distal
- O Abnormal neck posture,esp, retrocollis
- O Poor or absent response to levodopa
- O Early dysphagia and dysarthria
- O Early cognitive impairment consistent with PSP (apathy, impaired distraction, signs of frontal lobe dysfunction)

D. Features related to a diagnosis of MULTIPLE SYSTEM ATROPHY

Autonomic dysfunction	O Yes	O No	O Questionable
Cerebellar dysfunction including gait ataxia	O Yes	O No	O Questionable
Symptom onset after age 30	O Yes	O No	O DK

E. Features related to a diagnosis of CORTICOBASAL DEGENERATION

Sign(s) of cortical dysfunction	O Yes	O No	O Questionable	O DK
Asymmetric rigidity	O Yes	O No	O Questionable	O DK
Asymmetric dystonia	O Yes	O No	O Questionable	O DK
Focal reflex myoclonus	O Yes	O No	O Questionable	O DK

F. Features related to a diagnosis of ESSENTIAL TREMOR

Postural or kinetic tremor O Yes O Questionable   O DK

Characterize tremor: **a**. O Arms O Bilateral O Unilateral   O Postural O Kinetic
O Legs O Bilateral O Unilateral O Postural O Kinetic
O Voice
O Chin
O Head
O Tongue
O Other (specify):
b. O Isolated task-specific tremor   O Isolated position-specific tremor

Exclusionary/Modifying criteria for ET:

Any condition that might cause tremor?   O Yes   O No   ODK
If Yes: O PD   O Dystonia O Other(specify)
Was onset AFTER onset of postural or kinetic tremor?
O Yes   O No   ODK
Exposure to tremorgenic medication: O Yes   O No   ODK   If Yes, specify:
Other unequivocally abnormal
signs precluding diagnosis of ET: O Yes   O No   ODK
If Yes: 0 parkinsonism 0 other (specify):
Equivocal neurologic signs of doubtful
significance   O Yes   O No   ODK   If Yes,
specify:
Rate most severe postural or kinetic tremor: 0 I   0 2   0 3   0 4

Check boxes for medications

Category	Drug	Dose	Units

Anti-PD drugs

L-dopa	Sinemet		
	Sinemet CR		
Anticholinergic	Artane		
	Oxybutynim		
	Detrol		
	Bentyl		
	dicyclomine		
Amantadine			
MAO inhibitor	Selegiline		
DA agonist	pramipexole		
	pergolide		
	ropinirole		
	bromocriptine		
COMT inhibitor	entacapone		
	tolcapone		

Anti-Tremor drugs

beta blockers	systemic		
	ocular		
primidone			
carbonic anhydrase inhibitors			
gabapentin			

Drugs causing parkinsonism or tremor

DA receptor blockers	metoclopramide		
	other		
	Seroquel		
DA depletors	reserpine		
	tetrabenazine		
methyldopa			
beta agonists	systemic		
	inhaled		
lithium			
valproate			
tricyclic antidepressants			
antihistamines			
corticosteroids	systemic (do not code injected into joint or inhaled)		
thyroxine			
theophylline like agents			
cholinesterase inhibitors			

Most likely year of onset?_____
Year of diagnosis?_____

O NO NEUROLOGIC DISEASE

PARKINSON'S DISEASE

	by Gelb	byCAPIT
Definite Parkinson's disease	O	
Probable Parkinson's disease	O	O
Possible Parkinson's disease	O	O

O Likely Parkinson's disease but insufficient information to fulfill diagnostic criteria

Most likely year of onset?_____
Year of diagnosis?_____

SECONDARY PARKINSONISM, DUE TO

O Dopamine receptor blocking or dopamine depleting drugs O Toxicant induced, other *(specify cause below):*
O Vascular
O Other secondary *parkinsonism (specify cause below)*

Most likely year of onset?_____
Year of diagnosis?_____

DYSTONIA

O Primary generalized dystonia
O Focal dystonia *(Specify region):*   I
O Other dystonia *(Specify diagnosis below):*

Most likely year of onset?_____
Year of diagnosis?_____

PARKINSONISM PLUS SYNDROMES

(If applicable, indicate any subclassification below in the comments box)
O   Progressive supranuclear palsy
O   Olivopontocerebellar Atrophy
O   Multiple Systems Atrophy parkinsonism
O   Cortical-Basal-Ganglionic Degeneration
O   Multiple Systems Atrophy cerebellar
O   Other Parkinsonism Plus Syndrome (Specify diagnosis)
Most likely year of onset?_____
Year of diagnosis?_____

DEMENTIA

O Parkinson's disease with dementia (PDD)
O Dementia with Lewy bodies (DLB)
O Alzheimer's-like dementia with parkinsonism
O Alzheimer's-like dementia without parkinsonism
O Other dementia *(specify):*I

Most likely year of onset?_____
Year of diagnosis?_____

ESSENTIAL TREMOR

	Modified TRIG			TRIG 2000	
Definite	O		Classic	O
Probable	O		Indeterminate	O
Possible	O		Possible:	
Questionable	O		Type I	O
Not Essential Tremor	O		Type I, temporality unknown	O
			Type II	O
			Not Essential Tremor	O

Most likely year of onset?_____
Year of diagnosis?_____

OTHER NEUROLOGIC DISEASE

O Other neurological disease *(specify diagnosis)*
Most likely year of onset?_____
Year of diagnosis?_____

Do you suspect that this person may have early PD even if he/she does not fulfill diagnostic criteria for parkinsonism?

O Yes   O No   ON/A

Comments?   O Yes O No Comments